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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,182

11/14/2003

Eric Otto

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06/02/2006

NOVOZYMES NORTH AMERICA, INC.
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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,182	Applicant(s) OTTO ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/03/8/4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group VII, SEQ ID NO: 7 in the reply filed on March 20, 2006 is acknowledged.

SEQ ID Nos 1 – 6 are withdrawn from consideration. Claims 1 – 15 are pending and have been considered insofar as they read on the elected group/invention.

Claim Rejections - 35 USC § 112

2. Claims 2 – 3, 10 and 12 – 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, 3, 12 and 14 are rendered vague and indefinite for reciting “preferably” because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim 10 includes a trademark. It is noted that the use of the trademark RED STAR/LESEFFRE ETHANOL RED has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The use of parenthesis in claim 10 is confusing because it is unclear whether the limitations following the phrase are part of the claimed invention.

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Claim 13 is rendered vague and indefinite for reciting "such as" because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1 – 2, 6 – 9, 11 – 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lantero et al. (US 5231017 A).

Applicant claims a process for producing ethanol by fermentation, the process comprising a simultaneous saccharification and fermentation (SSF) step conducted at a temperature above 34C, in the presence of a glucoamylase and thermo-tolerant yeast. The temperature is at least 34.5C or 35C; the process further comprises recovering ethanol. A distilling step to obtain ethanol, wherein the SSF and distillation is carried out simultaneously or sequentially; the thermo-tolerant yeast is one which when fermenting at 35C, maintains at least 90% of ethanol yields and 90% of ethanol productivity during the first 70 hours of fermentation as compared to when fermenting at 32C; or is capable of producing at least 15% V/V alcohol from a corn mash

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comprising 34.5% solids. The SSF step is carried out in the presence of a protease and/or phytase, wherein the protease is a microbial protease, fungal protease, acid fungal protease derived from *Aspergillus niger*, or is a neutral or alkaline protease, such as one derived from a *Bacillus* strain. Applicant claims ethanol produced by the process.

Lantero teaches a method for producing ethanol by simultaneous saccharification and fermentation (abstract, col.3 line 44-54), at temperatures of 36C (example 1), in the presence of glucoamylase and thermo-tolerant yeast (col.3 line 20-54). Ethanol is recovered (abstract) by well known methods (or distillation) (col.3 line 44-54). The process is carried out in the presence of a protease derived from *Bacillus* or *Aspergillus niger* (col.2 line 8-25).

Although the reference does not teach the yeast is capable of the claimed yields, these traits are inherent to the yeast used in the methods. In addition, it is noted that the claimed Ethanol Red is a *Saccharomyces cerevisiae*, which is the preferred organism of Lantero (col.3). Thus, the yeast of Lantero must also exhibit the claimed characteristics.

Therefore, the reference anticipates the claimed subject matter.

5. Claims 1 – 2, 6 – 9 and 11 – 15 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Veit et al. (US 2002/0006647 A1).

Applicant claims a process for producing ethanol by fermentation, the process comprising a simultaneous saccharification and fermentation (SSF) step conducted at a temperature above 34C, in the presence of a glucoamylase and thermo-tolerant yeast. The temperature is at least 34.5C or 35C; the process further comprises recovering ethanol. A distilling step to obtain ethanol, wherein the SSF and distillation is carried out simultaneously or sequentially; the

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thermo-tolerant yeast is one which when fermenting at 35C, maintains at least 90% of ethanol yields and 90% of ethanol productivity during the first 70 hours of fermentation as compared to when fermenting at 32C; or is capable of producing at least 15% V/V alcohol from a corn mash comprising 34.5% solids. The SSF step is carried out in the presence of a protease and/or phytase, wherein the protease is a microbial protease, fungal protease, acid fungal protease derived from *Aspergillus niger*, or is a neutral or alkaline protease, such as one derived from a *Bacillus* strain. The phytase is microbial, derived from *Peniophra lycii* or *Aspergillus oryzae*. Applicant claims ethanol produced by the process.

Veit teaches a method for producing ethanol by simultaneous saccharification and fermentation (0010,0051) at a temperature of 60 – 95C or 30 – 65C (0020-0022), in the presence of glucoamylase (0034), thermo-tolerant yeast (0057), phytase (0033) derived from *Aspergillus oryzae* (0068), and/or protease from *Aspergillus niger* or *Bacillus* (0082-0091). Ethanol is recovered by distillation (0026-0051).

Although the reference does not teach the yeast is capable of the claimed yields, these traits are inherent to the yeast used in the methods. In addition, it is noted that the claimed Ethanol Red is a *Saccharomyces cerevisiae*, which is the preferred organism of Veit (claims). Thus, the yeast of Veit must also exhibit the claimed characteristics.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lantero in view of Neilsen et al. (US 6255084 B1).

Applicant claims a process for producing ethanol by fermentation, the process comprising a simultaneous saccharification and fermentation (SSF) step conducted at a temperature above 34C, in the presence of a glucoamylase and thermo-tolerant yeast. The temperature is at least 34.5C or 35C; the process further comprises recovering ethanol. A distilling step to obtain ethanol, wherein the SSF and distillation is carried out simultaneously or sequentially; the thermo-tolerant yeast is one which when fermenting at 35C, maintains at least 90% of ethanol yields and 90% of ethanol productivity during the first 70 hours of fermentation as compared to

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when fermenting at 32C; or is capable of producing at least 15% V/V alcohol from a corn mash comprising 34.5% solids. The SSF step is carried out in the presence of a protease and/or phytase, wherein the protease is a microbial protease, fungal protease, acid fungal protease derived from *Aspergillus niger*, or is a neutral or alkaline protease, such as one derived from a *Bacillus* strain. Applicant claims ethanol produced by the process. The glucoamylase is derived from *Talaromyces emersonii*, specifically CBS 793.97; has an amino acid sequence comprising a partial sequence of seq id no 7; with an identity of at least 60%, or is a variant thereof. The yeast is RED STAR/LESAFFRE ETHANOL RED.

Lantero teaches a method for producing ethanol by simultaneous saccharification and fermentation (abstract, col.3 line 44-54), at temperatures of 36C (example 1), in the presence of glucoamylase and thermo-tolerant yeast (col.3 line 20-54). Ethanol is recovered (abstract) by well known methods (or distillation) (col.3 line 44-54). The process is carried out in the presence of a protease derived from *Bacillus* or *Aspergillus niger* (col.2 line 8-25).

Although the reference does not teach the yeast is capable of the claimed yields, these traits are inherent to the yeast used in the methods. In addition, it is noted that the claimed Ethanol Red is a *Saccharomyces cerevisiae*, which is the preferred organism of Lantero (col.3). Thus, the yeast of Lantero must also exhibit the claimed characteristics.

The reference does not teach the process wherein the glucoamylase is that claimed, or the specific yeast as claimed. However, Nielsen teaches a thermostable glucoamylase that is suitable for simultaneous saccharification (abstract, col.3). Specifically, Nielsen teaches a glucoamylase that is isolated from *T. emersonii* CBS 793.97 with the claimed SEQ ID and partial sequence (col.2, sequence listing). At the time of the claimed invention, one of ordinary skill in the art

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would have been motivated by Nielsen to use the glucoamylase of Nielsen in the methods of Lantero for its thermo-tolerance and disclosed advantage in continuous saccharification processes (col.3). Furthermore, as stated above, Ethanol Red is a *Saccharomyces cerevisiae*, which is the preferred organism of Lantero (col.3). While Lantero does not specifically identify the claimed brand of yeast, the yeasts are clearly the same genus species, which are tolerant of high temperatures. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lantero to use any name brand yeast of *S. cerevisiae*, and that is thermo-tolerant.

9. Claims 1 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veit in view of Neilsen.

Applicant claims a process for producing ethanol by fermentation, the process comprising a simultaneous saccharification and fermentation (SSF) step conducted at a temperature above 34C, in the presence of a glucoamylase and thermo-tolerant yeast. The temperature is at least 34.5C or 35C; the process further comprises recovering ethanol. A distilling step to obtain ethanol, wherein the SSF and distillation is carried out simultaneously or sequentially; the thermo-tolerant yeast is one which when fermenting at 35C, maintains at least 90% of ethanol yields and 90% of ethanol productivity during the first 70 hours of fermentation as compared to when fermenting at 32C; or is capable of producing at least 15% V/V alcohol from a corn mash comprising 34.5% solids. The SSF step is carried out in the presence of a protease and/or phytase, wherein the protease is a microbial protease, fungal protease, acid fungal protease derived from *Aspergillus niger*, or is a neutral or alkaline protease, such as one derived from a

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Bacillus strain. The phytase is microbial, derived from *Peniophora lycii* or *Aspergillus oryzae*.

Applicant claims ethanol produced by the process. The glucoamylase is derived from *Talaromyces emersonii*, specifically CBS 793.97; has an amino acid sequence comprising a partial sequence of seq id no 7; with an identity of at least 60%, or is a variant thereof. The yeast is RED STAR/LESAFFRE ETHANOL RED

Veit teaches a method for producing ethanol by simultaneous saccharification and fermentation (0010,0051) at a temperature of 60 – 95C or 30 – 65C (0020-0022), in the presence of glucoamylase (0034), thermo-tolerant yeast (0057), phytase (0033) derived from *Aspergillus oryzae* (0068), and/or protease from *Aspergillus niger* or *Bacillus* (0082-0091). Ethanol is recovered by distillation (0026-0051).

Although the reference does not teach the yeast is capable of the claimed yields, these traits are inherent to the yeast used in the methods. In addition, it is noted that the claimed Ethanol Red is a *Saccharomyces cerevisiae*, which is the preferred organism of Veit (claims). Thus, the yeast of Veit must also exhibit the claimed characteristics.

The reference does not teach the process wherein the glucoamylase is that claimed, or the specific yeast as claimed. However, Nielsen teaches a thermostable glucoamylase that is suitable for simultaneous saccharification (abstract, col.3). Specifically, Nielsen teaches a glucoamylase that is isolated from *T. emersonii* CBS 793.97 with the claimed SEQ ID and partial sequence (col.2, sequence listing). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nielsen to use the glucoamylase of Nielsen in the methods of Veit for its thermo-tolerance and disclosed advantage in continuous saccharification processes (col.3). Furthermore, as stated above, Ethanol Red is a *Saccharomyces cerevisiae*, which is the preferred

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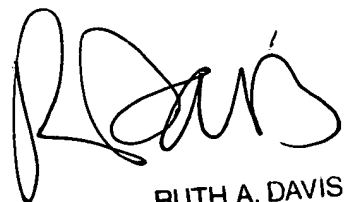
organism of Veit (claims). While Veit does not specifically identify the claimed brand of yeast, the yeasts are clearly the same genus species, which are tolerant of high temperatures. Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Veit to use any name brand yeast of *S. cerevisiae*, and that is thermo-tolerant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 30, 2006
AU 1651



RUTH A. DAVIS
PATENT EXAMINER